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VERIFICATION OF A TRANSLATION

I, Charles Edward SITCH BA,

Deputy Managing Director of RWS Group Ltd UK Translation Division, of Europa House, Marsham Way, Gerrards Cross, Buckinghamshire, England declare:

That the translator responsible for the attached translation is knowledgeable in the German language in which the below identified international application was filed, and that, to the best of RWS Group Ltd knowledge and belief, the English translation of the amended sheets of the international application No. PCT/EP2004/000451 is a true and complete translation of the amended sheets of the above identified international application as filed.

I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application issued thereon.

Date: June 22, 2005

Signature : 

For and on behalf of RWS Group Ltd

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England.

New claims

1. An implantable device (1) to be used in the human and/or animal body for occluding or partially occluding defect openings, hollow spaces, organ tracts, etc. or for creating a defined connecting opening between walls, organs, hollow spaces, etc., with a support structure which has a great length-to-width ratio along an axis (63) in a first operating state (primary shape) while having a smaller length-to-width ratio along said axis (63) in a second operating state (secondary shape), and the support structure having a proximal portion (20) and a distal portion (30), the support structure being formed from a single wire-like element (10) by intercoiling and/or intertwining and/or interweaving in the manner of a tissue and/or scrim and/or net, characterized in that the proximal portion (20) and/or distal portion (30) in the secondary shape is substantially flat in a disk shape or ring shape or at least bent round in the edge area or bent back toward the other portion or bent outward from an intermediate portion (40) connecting the distal and proximal portions, so that a delimited inner space (27) is formed.

2. The implantable device (1) as claimed in claim 1, characterized in that the proximal portion (20) and the distal portion (30) of the support structure in the secondary shape are placed flat and partially on top of one another so that an occlusion or partial occlusion of openings delimited laterally by walls, especially in the area of valve flaps, is permitted in the human or animal body.

3. The implantable device (1) as claimed in one of

the preceding claims, characterized in that at least a partial area of the implantable device (1) is designed folded in or is able to be folded in.

4. The implantable device (1) as claimed in one of the preceding claims, characterized in that, in the secondary shape of the support structure, a central through-opening (50) remains in the implantable device for partial occlusion of an opening (2).

5. The implantable device (1) as claimed in one of the preceding claims, characterized in that a through-opening (50, 51) provided inside the implantable device (1) is arranged eccentrically therein.

6. The implantable device (1) as claimed in one of the preceding claims, characterized in that the proximal portion (20) and the distal portion (30) are of disk-shaped configuration with an intermediate portion (40) arranged between them, the intermediate portion (40) having a reduced diameter compared to the proximal portion (20) and/or distal portion (30), and the through-opening (50, 51) provided inside the implantable device (1) being arranged eccentrically therein.

7. The implantable device (1) as claimed in one of the preceding claims, characterized in that the dimensions and shape of the implantable device, of a through-opening (50, 51) inside the implantable device (1) and/or of the edge of the implantable device (1) are selected or adjusted specifically to the application.

8. The implantable device (1) as claimed in one of the preceding claims, characterized in that at least one portion of the support structure in the

primary and/or secondary shape is asymmetrically and/or irregularly configured.

9. The implantable device (1) as claimed in claim 8, characterized in that the material concentration and/or the material thickness inside the support structure is different from portion to portion.

10. The implantable device (1) as claimed in claim 9, characterized in that partial areas of the support structure are formed from a material of different diameter, or partially different diameters of the material of the support structure are formed by provision of several wires.

11. The implantable device (1) as claimed in one of the preceding claims, characterized in that the amount of material in the edge area of the implantable device is adapted to the desired mechanical properties, in particular a concentration of material being provided in the edge area (23, 33) of the device (1) for partial stiffening.

12. The implantable device (1) as claimed in one of the preceding claims, characterized in that the two ends (11, 12) of the wire-like element (10) are arranged on one of the ends of the support structure or are integrated into the surface of the support structure.

13. The implantable device (1) as claimed in one of the preceding claims, characterized in that the end (24) of the proximal portion (20) is open or partially closed or completely closed, in particular by provision of a plate element.

14. The implantable device (1) as claimed in one of the preceding claims, characterized in that the

end (24, 34) of the distal portion (30) and/or proximal portion (20) has one or more hoops (26) or loops (22, 32) which are interlocked and/or arranged alongside one another and/or interlaced, in particular with a substantially uniform edge being formed.

15. The implantable device (1) as claimed in one of the preceding claims, characterized in that the support structure is designed as a two-part or multi-part unit connected to one another to form one part and formed from a wire-like element (10).

16. The implantable device (1) as claimed in claim 15, characterized in that the individual parts of the support structure are designed uniformly, corresponding to one another or differing from one another.

17. The implantable device (1) as claimed in one of the preceding claims, characterized in that the support structure of the implantable device (1) in the primary shape or basic coil shape is configured like a stent.

18. The implantable device (1) as claimed in one of the preceding claims, characterized in that the ends (11, 12) of the wire-like element (10) are connected or can be suitably connected to one another, in particular by attachment of a further element (100, 103), by twisting, adhesive bonding, welding, soldering, or another connection method.

19. The implantable device (1) as claimed in one of the preceding claims, characterized in that one or more membranes (72, 73) or membrane-like or membrane-forming structures are incorporated into the support structure or applied to it.

20. The implantable device (1) as claimed in claim 19, characterized in that the membrane-forming structure is formed by inweaving of at least one filament (70), in particular a filament made of a flexible weavable material, in particular a plastic, a renewable raw material or metal, in particular one or more Dacron filaments and/or carbon fibers.

21. The implantable device (1) as claimed in claim 19 or 20, characterized in that the membrane-forming structure is made of a material with a cross section differing from that of the wire-like element (10) or has a braid, scrim or weave with filaments of different diameter.

22. The implantable device (1) as claimed in claim 19, 20 or 21, characterized in that the membrane-like structure is formed by dipping the support structure into a film-forming material, in particular a natural or synthetic polymer formed from one or more monomers, in particular by polyaddition, polymerization or polycondensation, in particular a polycarbonate, polyester, polyamide, polyolefin or polyurethane.

23. The implantable device (1) as claimed in one of claims 19 through 22, characterized in that the membrane-like structure or membrane is formed from a weave, scrim or other textile and is provided in the edge area with protruding arms (74) for threading and/or securing on the support structure, in particular by sewing, adhesive bonding, welding, crimping, or another securing method.

24. The implantable device (1) as claimed in one of claims 19 through 23, characterized in that the membrane(s) and membrane-like or membrane-forming

structure(s) is/are arranged proximally, distally or substantially centrally in the support structure.

25. The implantable device (1) as claimed in one of the preceding claims, characterized in that, instead of the support structure formed from a wire-like element, the implantable device is formed from a cut tube, in particular a laser-cut tube, in particular from a tube made of a biocompatible material, in particular nitinol or a polycarbonate.

26. The implantable device (1) as claimed in one of the preceding claims, characterized in that the material of the support structure is chemically and/or mechanically treated in at least a partial area, in particular etched, electropolished, microground or otherwise treated.

27. The implantable device (1) as claimed in one of the preceding claims, characterized in that the wire-like element (10) of the implantable device (1) is made of a biocompatible material, in particular a metal or a metal alloy, in particular a high-grade steel, or a plastic, for example polycarbonate, in particular a shape-memory material such as nitinol.

28. A positioning system, especially for an implantable device as claimed in one of claims 1 through 27, with an advancing element (5), a guide wire (6, 9) and/or inner mandrel and at least one retaining wire (80, 81), the guide wire (6) and the at least one retaining wire (80, 81) being used for cooperating with a proximal end of the implantable device (1), and the implantable device (1) being transformable from a primary shape into a secondary shape and vice versa by moving the

retaining wire (80, 81) and the guide wire (6) relative to the advancing element (5).

29. The positioning system as claimed in claim 28, characterized in that the retaining wire or retaining wires (80, 81) is/are threaded or can be threaded through one or more loops or hoops at the end of the proximal portion (20) of the implantable device (1) and are connected or can be connected to the guide wire (6) and/or inner mandrel.

30. The positioning system as claimed in claim 28 or 29, characterized in that a chain of retaining wire loops is formed which is threaded or can be threaded through one or more loops or hoops at the end of the proximal portion (20) and/or distal portion (30) of the support structure.

31. The positioning system as claimed in claim 28, 29 or 30, characterized in that a guide wire (9) and an extraction wire (90) are provided for extracting the implantable device (1) from the implantation site in the human or animal body, the extraction wire (90) being able to be made into a loop or hoop (91) and able to be threaded through at least one hoop or loop at one end (24, 34) of the support structure.

32. A positioning system, especially for an implantable device as claimed in one of claims 1 through 27, with an advancing element (5), with an auxiliary structure (120) having a great length-to-width ratio along an axis in a first operating state (primary shape) while having a smaller length-to-width ratio along said axis in a second operating state (secondary shape) for aiding the deployment of the proximal portion (20) of the support structure of the implantable device (1),

and with at least one connection device (130, 131, 132) for connecting the proximal end (24) of the implantable device (1) and the distal end (121) of the auxiliary structure (120).

33. The positioning system as claimed in claim 32, characterized in that the connection device has at least one retaining wire, in particular three retaining wires (130, 131, 132).

34. The positioning system as claimed in claim 33, characterized in that the at least one retaining wire (130, 131, 132) is threaded or can be threaded through one or more loops (22, 123) or hoops at the end of the proximal end (24) of the implantable device (1) and of the distal end (121) of the auxiliary structure (120).

35. A set consisting of a positioning system as claimed in one of claims 28 through 31 and of one or more implantable devices as claimed in one of claims 1 through 27 or of a positioning system as claimed in one of claims 32 through 34 and one or more implantable devices as claimed in one of claims 1 through 27.

36. A method for producing an implantable device (1) as claimed in one of claims 1 through 27, characterized by the following steps:

- coiling a support structure basic coil shape from a wire-like element (10) by intercoiling and/or intertwining and/or interweaving in the manner of a tissue and/or scrim and/or net,
- annealing the support structure basic coil shape in order to stabilize the shape,
- forming the support structure from the basic coil shape into a desired secondary shape, and
- annealing the support structure secondary shape in order to stabilize and imprint the shape.

37. The method as claimed in claim 36, characterized in that the first coiling step is done by hand.